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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/528,911 | 10/07/2005 | Graham Edmund Kelly | 700136.402USPC | 6404 |
| 500 7590 11/30/2007 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104 | | | EXAMINER HOLT, ANDRIAE M | |
| | | | ART UNIT 1616 | PAPER NUMBER |
| | | | MAIL DATE 11/30/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/528,911 | Applicant(s) KELLY ET AL. | |
| | Examiner Andriae M. Holt | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9 are pending in the application. Claims 1-9 will be examined on the merits.

Priority

Priority to PCT/AU03/01265 filed on September 23, 2003, which claims priority to Australian Application Numbers 2002951572 and 2003900236 filed on September 23, 2002 and January 21, 2003, respectively, is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treatment of skin photoageing or actinic damage of skin by administering one or more compounds of the general formula II, does not reasonably provide enablement for a method of prevention of skin photoageing or actinic damage of skin by administering one or more compounds of the general formula II. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, method of treatment of skin photoageing or actinic damage of skin by administering one or more compounds of the general formula II. However, Applicant is purporting to have a method of treatment of skin photoageing or actinic damage of skin by administering one or more compounds of the general formula II useful for the prevention of skin photoageing or actinic damage of skin by administering one or more compounds of the general formula II. Therefore, applicant is enabled for a method of treatment of skin photoageing or actinic damage of skin by administering one or more compounds of the general formula II, not for prevention of those disorders.

2) Nature of the invention

The nature of the invention is directed to a method for the treatment of skin photoageing or actinic damage of skin by administering one or more compounds of the general formula II.

3) State of, or the amount of knowledge in, the prior art

The art teaches that isoflavones, particularly, can inhibit the harmful effect of UVR exposure to the human skin using an effective amount of genistein mixed with a variety of carriers and skin treatment compositions (Wei US 5,824,702).

4) Predictability or lack thereof in the art: The skilled artisan would view that treatment to prevent skin photoageing or actinic damage of skin to be totally, absolutely, or permanently, as highly unpredictable, and so as to not even occur at the first time, is highly **unpredictable**.

5) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to preventing skin photoageing or actinic damage of skin by administering to a subject one or more compounds of the general formula II, particularly, equol. Applicant has not provided clear and convincing examples on the prevention of skin photoageing or actinic damage of skin. Applicant has shown in the working examples treatment and potentiated protection, not prevention.

Therefore, in view of the Wands factors, e.g., the state of the art, absence of working examples, predictability or lack of thereof, and the nature of the invention discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in **undue experimentation** to formulate a method of prevention of skin photoageing or actinic damage of the skin by administering to a subject one or more compounds of general formula II.

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Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 provides for the use of compounds of the formula II for the prevention and/or treatment of skin photoageing or actinic damage of skin associated with UV exposure, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-4 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 2-3 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claims 2-3 and 7-8 contain improper Markush language. The claims read "selected from". The claims should read "selected from group consisting of". Example claim 7 should read, "skin photoageing selected from group consisting of lines, wrinkles, freckles, yellowing of skin, skin stretching, dilated capillaries, cherry red spots and dry complexion".

Claim Rejections - 35 USC § 102

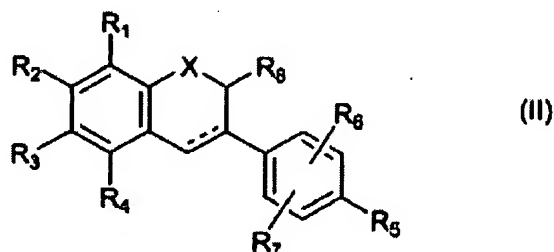
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

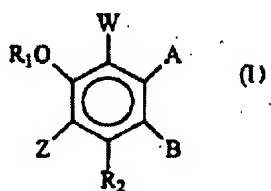
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kelly et al. (WO 99/36050).

Applicant claims a method for the treatment of skin photoageing or actinic damage of skin which comprises administering to a subject one or more compounds of the general formula (II)



Kelly et al. disclose an invention related to methods of protecting the skin from UV induced immunosuppression and UV induced skin damage, such as that resulting from exposure to the sun. Kelly et al. disclose that certain isoflavone compounds when applied to the skin subsequent to UV exposure or for oral administration prior to or following UV exposure, in the form of an after-sun composition, protect the skin from UV induced immunosuppression and UV induced skin damage (page 3, lines 26-31). Kelly et al. disclose that a composition for application to the skin following UV exposure or for oral administration prior to or following UV exposure, which composition comprises a compound of the general Formula (I)



Kelly et al. disclose preferable compounds of the formula (I) are selected from compounds on pages 6-8. Kelly et al. further disclose that particularly preferred compounds of the formula (I) for use in compositions and methods are equol (compound 10 when = is a single bond) and dehydroequol (compound 10 when = is a double bond) (page 13, lines 18-20) (compositions of formula (II), equol and dehydroequol, instant invention).

Kelly et al. disclose UV induced skin damage refers to any sunlight or other UV damage which effects skin, whether a human or animal. Kelly et al. further disclose such damage includes erythema (reddening and swelling of the skin, often referred to

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as sunburn), photoageing of the skin such as hyper keratinization and elastosis and skin lesions such as precancerous and cancerous lesions, for example actinic keratoses and pre-malignant and malignant skin cancers (page 12, lines 21-26) (skin photoageing or actinic damage, actinic keratoses, instant invention). Kelly et al. disclose that the photoageing phenomenon includes thickening of skin, drying of skin, increased skin pigmentation, skin spots and skin lesions (page 2, lines 10-12)(photoageing, lines, dry complexion, cherry red spots, instant invention). Kelly et al. disclose the invention is a method of protecting skin from UV induced immunosuppression and UV induced skin damage which comprises applying to the skin of a subject after UV exposure a composition which comprises a compound of the formula (1) with a dermatologically acceptable carrier (page 12, lines 28-30—age 13, lines 1-2) (applied topically, instant invention). Kelly et al. further disclose compositions are applied to the skin following sun exposure, and are generally applied after each exposure to the skin, or alternatively at the end of the day following a series of exposure of the skin to sun (applied topically before and/or after skin exposure, instant invention). Kelly et al. disclose the invention is a method for protecting skin against UV induced immunosuppression and UV induced skin damage by administering orally to a subject either before and/or after UV exposure a compound of the formula (I) (page 13, lines 4-7) (administered orally, before and/or after skin exposure, instant invention). Kelly et al. disclose in example 2 that dehydroequol and equol have significant activity in amelioration of UV induced immunosuppression (pages 16, lines 1-24-page 17, lines 1-28).

Claims 1-2, 4-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorbach (US 6,060,070).

Gorbach discloses a topical use of purified isoflavonoids, which are constituents of soy beans and other plants such as clover, to effectively treat and prevent symptoms of aging skin, such a wrinkles (col. 1, lines 37-40). Gorbach discloses purified isoflavonoids which may be administered according to the invention include equol (col. 1, lines 44-47) (formula II, equol, instant invention). Gorbach discloses a method of treating in a person, one or more symptoms of aging skin, e.g. wrinkles, by applying to the person's skin a composition containing a dermatologically acceptable base containing between 1 and 40 mg purified isoflavonoid per gram of base (photoageing, wrinkles, instant invention) (col. 1, lines 49-55). Gorbach discloses that preferred topical formulations are creams, ointments, lotions, emollient creams and ointments, moisturizing lotions, and gels (col. 1, lines 60-64) (topical application, instant invention). Gorbach further discloses a method of treating one or more symptoms of aging skin in a male person or female person by administering orally a composition containing one or more purified isoflavonoids selected from equol (col. 2, lines 3-14) (oral administration, instant invention). Gorbach discloses the topical composition should be left on the skin for a sufficient period of time to allow the isoflavonoid to be substantially absorbed into the skin and the capillaries supplying the skin (col. 2, lines 53-57). Gorbach does not specifically point out that the symptoms of aging skin is photoageing, however it is inherent that some symptoms of aging skin are caused by exposure to the sun.

None of the claims are allowed.

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Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Andriae M. Holt
Patent Examiner


SHELLEY A. DODSON
PRIMARY EXAMINER